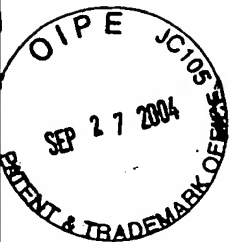


JFW

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Name: Nada Jain

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Docket No. 1010/0100US3

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Leo J. Romanczyk, et al.

Filed: March 1, 2004

Group Art Unit:

Serial No: 10/790,268

Examiner:

For: Pharmaceutical Compositions

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In order to comply with 37 CFR 1.97 and 1.98, attached hereto is a copy of Form PTO-1449 and copies of the documents listed thereon.

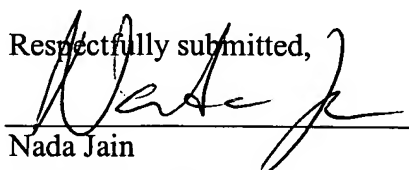
Applicants respectfully request the Examiner's consideration of the cited references and entry into the record of this application and that it be cited of record in the prosecution history of the present application by initialing Form PTO-1449 next to the document. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

The present Information Disclosure Statement is being submitted in compliance with 37 CFR 1.56, but the citation of such document is not to be construed as an admission that such document is necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner, in the normal course of examination, will make an independent search and will determine the best prior art consistent with 37 CFR 1.104 and, in the course of each search, will review for relevance every document cited on the attached form even if not initialed.

The present Information Disclosure Statement has been submitted prior to the receipt of an Office Action in this application. Accordingly, no fee is due. However, in the event that a first Office Action was mailed on or before the date of submission of this disclosure statement, the Commissioner is hereby authorized to charge any fees to deposit Account No. 50-2549.

Date: September 24, 2004

Respectfully submitted,

  
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## INFORMATION DISCLOSURE STATEMENT

Inventors: Leo J. Romanczyk, et al.

(Use several sheets if necessary)

Docket No. 1010/0100US3

## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL |   | DOCUMENT<br>NUMBER | DATE    | NAME              | CLASS | SUBCLASS | FILING DATE IF<br>APPROPRIATE |
|---------------------|---|--------------------|---------|-------------------|-------|----------|-------------------------------|
|                     | 1 | 4,797,421          | 1/1989  | Ariga et al.      | 514   | 844      | 9/22/87                       |
|                     | 2 | 4,698,360          | 10/1987 | Masquelier        | 514   | 456      | 4/9/85                        |
|                     | 3 | 5,925,355          | 7/1999  | Chatterjee et al. | 424   | 765      | 7/28/94                       |
|                     |   |                    |         |                   |       |          |                               |

## FOREIGN PATENT DOCUMENTS

| EXAMINER<br>INITIAL |   | DOCUMENT NUMBER | DATE   | COUNTRY | TRANSLATION    |
|---------------------|---|-----------------|--------|---------|----------------|
|                     | 4 | 0 096 007 B1    | 7/1987 | EP      | Yes            |
|                     | 5 | 4-190774        | 7/1992 | JP      | Yes            |
|                     | 6 | 5292885 A       | 9/1993 | JP      | Yes - Abstract |

## OTHER DOCUMENTS

| EXAMINER<br>INITIAL |    | AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.   |
|---------------------|----|--|
|                     | 7  | Cheng, Juei-Tang, et al., <i>Antihypertensive Principles from the Leaves of Melastoma Candidum</i> , <u>Planta Med.</u> 59:405-407 (1993)  |
|                     | 8  | Chang, Wen-Chang, et al., <i>Inhibition of Platelet Aggregation and Arachidonate Metabolism in Platelets by Procyanidins, Prostaglandins Leukotrienes and Essential Fatty Acids</i> , 38, 181-188 (1989)   |
|                     | 9  | Roddewig, Von c., et al., <i>Reaktion der lokalen Myokarddurchblutung von wachen Hunden und narkotisierten Katzen auf orale und parenterale Applikation einer Crataegusfraktion (oligomere Procyanidine)</i> , <u>Arzneim.-Forsch./Drug Res.</u> 27 (II), No. 7, 1407-1410 (1977) - with English summary translation ( <i>with translation</i> ) |
|                     | 10 | Meunier, Marie-Therese, et al., <i>Inhibition of Angiotensin I Converting Enzyme by Flavanolic Compounds: In Vitro and In Vivo Studies</i> , <u>Planta Medica</u> 53:1, 1-120 (1987)   |
|                     | 11 | Okuda, Takuo, et al., <i>Pharmacologically Active Tannins Isolated from Medicinal Plants</i> , <u>Plant Polyphenols</u> , Plenum Press, New York (1992)  |
|                     | 12 | Inokuchi, Jin-ichi, et al., <i>Antihypertensive Substance in Seeds of Areca Catechu L.</i> , <u>Life Sciences</u> , Vol. 38, 1375-1382 (1986)  |
|                     | 13 | Gali, H.U., et al., <i>Comparison of the Inhibitory Effects of Monomeric, Dimeric, and Trimeric Procyanidins on the Biochemical Markers of Skin Tumor Promotion in Mouse Epidermis in vivo</i> , <u>Planta Med.</u> 60, 235-239 (1994)   |
|                     | 14 | Kashiwada, Yoshiki, <i>Antitumor Agents, 129. Tannins and Related Compounds as Selective Cytotoxic Agents</i> , <u>Journal of Natural Products</u> 55:8, 1033-1043 (1992)  |
|                     | 15 | Rohrbach, Michael S., et al., <i>Structural Determinants of the Platelet Agonist Activity of Cotton Bract Condensed Tannin</i> , <u>Environmental Research</u> 52, 199-209 (1990)  |

|    |  |
|----|--|
| 16 | Vennat, Brigitte, et al., <i>Procyanidins from the Roots of Fragaria vesca: Characterization and Pharmacological Approach</i> , <u>Chem. Pharm. Bull.</u> 36:828-833 (1988)  |
| 17 | Zafirov, D., et al., <i>Antiexudative and Capillaritonic Effects of Procyanidines Isolated from Grape Seeds (V. Vinifera)</i> , <u>Acta Physiologica et Pharmacologica Bulgarica</u> Vol. 16 No. 3 pp. 50-54 (1990)  |
| 18 | Fitzpatrick, David et al., <i>Endothelium-dependent Vasorelaxing Activity of Wine and Other Grape Products</i> , <u>Am. J. Physiol.</u> 265 (Heart Circ. Physiol. 34) H774-H778 (1993)   |
| 19 | Khushbaktova, Z.A., et al., <i>Study of Hypolipidemic Properties of Polymeric Proanthocyanidins from Plants Used in Folk Medicine</i> , <u>Medicinal Plants</u> (UDC615.322:615.272.4.012.1) (1987)(with translation)  |
| 20 | Wegrowski, J. et al., <i>The Effect of Porcyanidolic Oligomers on the Composition of Normal and hypercholesterolemic Rabbit Aortas</i> , <u>Biochem. Pharmacol.</u> Vol. 33 No. 21 pp. 3491-3497 (1984)  |
| 21 | Gabor, M. and Razga, Z., <i>Effect of Benzopyrone Derivatives on Simultaneously Induced Croton Oil Ear Oedema and Carrageenin Paw Oedema in Rats</i> , <u>Acta Physiologica Hungarica</u> Vol. 77 (3-4) pp. 197-207 (1991)   |
| 22 | Villar, A., et al., <i>A Hypotensive Procyanidin-Glycoside from Rhamnus Lycioides ssp. Lycioides</i> , <u>Journal of Ethnopharmacology</u> Vol. 30 pp. 205-214 (1986)  |
| 23 | Ariga, Toshiaki and Yuasa, Katsumi, <i>Antioxidative Properties of Oligomeric Proanthocyanidins and Their Applications</i> , <u>Fragrance Journal, Special Edition/Functions and Applications in Recent Food Materials</u> (1994) (with translation)   |
| 24 | Rong, Yongqi, et al., <i>Pycnogenol Protects Vascular Endothelial Cells from T-butyl Hydroperoxide Induced Oxidant Injury</i> , <u>Biotechnol Ther</u> Vol. 5 Nos. 3-4 pp. 117-126 (1994-95)   |
| 25 | Sanz, M.J., et al., <i>Isolation and Hypotensive Activity of a Polymeric Procyanidin Fraction from Pistacia Lentiscus L.</i> , <u>Pharmazie</u> Vol. 47 pp. 466-467 (1992)   |
| 26 | Sanz, M.J., et al., <i>Pharmacological Actions of a New Procyanidin Polymer from Pistacia Lentiscus L.</i> , <u>Pharmazie</u> 48, 152-153 (1993)   |
| 27 | Blazso, G., et al., <i>Oedema-Inhibiting Effect of Procyanidin</i> , <u>Acta Physiologica Academiae Scientiarum Hungaricas</u> 56(2), 235-240 (1980)   |
| 28 | Miyamoto, Kenichi et al., <i>Relationship Between the Structures and the Antitumor Activities of Tannins</i> , <u>Chem Pharm Bull</u> Vol. 35 pp. 814-822 (1987)   |
| 29 | Negre-Salvayre, Anne et al., <i>Ultraviolet-treated Lipoproteins as a Model System for the Study of the Biological Effects of Lipid Peroxides on Cultured Cells. III. The Protective Effect of Antioxidants (Probucol, Catechin, Vitamin E) Against the Cytotoxicity of Oxidized LDL Occurs in Two Different Ways</i> , <u>Biochimica et Biophysica Acta</u> , 1096:291-300 (1991) |
| 30 | Ho, Chi-Tang et al., <i>Antioxidative Effect of Polyphenol Extract Prepared from Various Chinese Teas</i> , <u>Preventive Medicine</u> Vol. 21 pp. 520-525 (1992)  |
| 31 | W.C. Chang et al., <i>Inhibition of Platelet Activation and Endothelial Cell Injury by Polyphenolic Compounds Isolated from Lonicera Japonica Thunb.</i> , <u>Prostaglandins Leukotrienes and Essential Fatty Acids</u> (1991)   |
| 32 | Ratty, A.K. et al., <i>Interaction of Flavonoids with 1,1-Diphenyl-2-Picrylhydrazyl Free Radical, Liposomal Membranes and Soybean Lipoxygenase-1</i> , <u>Biochemical Pharmacology</u> Vol. 37 No. 6 pp. 989-995 (1988)  |
| 33 | Koch, H.P., et al., <i>Influence of Silymarin and Some Flavonoids on Lipid Peroxidation in Human Platelets</i> , <u>Meth and Find Exptl Clni Pharmacol</u> 7(1):13-18 (1985)   |
| 34 | Xie, Bijun, et al., <i>Antioxidant Properties of Fractions and Polyphenol Constituents from Green, Oolong and Black Teas</i> , <u>Proc Natl Sci Conc Rebut China - Part B</u> Vol. 17 No. 2 pp. 77-84 (1993)   |
| 35 | Janero, David R., et al., <i>Influence of Cardioprotective Cyclooxygenase and Lipoxygenase Inhibitors on Peroxidative Injury to Myocardial-Membrane Phospholipid</i> , <u>Biochemical Pharmacology</u> , Vol. 38, No. 24, 4381-4387 (1989)   |

|  |    |   |
|--|----|---|
|  | 36 | Bamforth, Kathleen J., et al., <i>Common Food Additives are Potent Inhibitors of Human Liver 17<math>\alpha</math>-Ethinylloestradiol and Dopamine Sulphotransferases</i> , <u>Biochemical Pharmacology</u> , Vol. 46, No. 10, 1718-1720 (1993)                                     |
|  | 37 | Nakadate, Teruo, et al., <i>Effects of Flavonoids and Antioxidants on 12-O-Tetradecanoyl-Phorbol-13-Acetate-Caused Epidermal Ornithine Decarboxylase Induction and Tumor Promotion in Relation to Lipoxygenase Inhibition by These Compounds</i> , <u>Gann</u> , 75, 214-222 (1984) |
|  | 38 | Brattig, N. W. et al., <i>Immunoenhancing Effect of Flavonoid Compounds on Lymphocyte Proliferation and Immunoglobulin Synthesis</i> , <u>J. Immunopharmac</u> Vol. 6 No. 3 pp. 205-215 (1984)  |

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|---|-----------------|
| EXAMINER  | DATE CONSIDERED |
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |                 |

Form PTO-1449 [2-2]